The opinion in support of the decision being entered today was $\underline{\text{not}}$ written for publication and is $\underline{\text{not}}$ binding precedent of the Board.

Paper No. 18

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte JOSEPH R. PARADIS

Appeal No. 2001-2363 Application 09/073,022

ON BRIEF

Before FRANKFORT, McQUADE, and NASE, <u>Administrative Patent</u> Judges.

FRANKFORT, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal from the examiner's final rejection of claims 10 through 19 and 21 through 30, all of the claims remaining in this application. Claims 1 through 9 and 20 have been canceled. In the supplemental answer (page 2, Paper No. 17, mailed September 10, 2002), the examiner has indicated

that claims 10 through 19 now stand allowed and that claim 26 is "allowable." Thus, only claims 21 through 25 and 27 through 30 remain for our consideration on appeal.

Appellant's invention relates to a method of, and coupling systems for, permitting the transfer of materials from one unit to another and, more particularly, to coupling units used in the medical field to permit a blunt or needleless cannula to safely remove material from a vial while limiting the extent to which pathogens can enter the cannula and/or vial after coupling is effected. Independent claims 21 and 30 are representative of the subject matter on appeal, and a copy of those claims is attached to this decision.

The sole prior art reference of record relied upon by the examiner is:

Brony 5,620,434 Apr. 15, 1997

Claims 21 through 24 and 27 through 30 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Brony.

Claim 25 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Brony.

Rather than reiterate the conflicting viewpoints advanced by appellant and the examiner regarding the above-noted rejections, we refer to the supplemental examiner's answer (Paper No. 17, mailed September 10, 2002) and appellant's revised appeal brief (Paper No. 14, filed March 5, 2001) for a full exposition thereof.

OPINION

Having carefully reviewed the anticipation and obviousness issues raised in this appeal in light of the record before us, we have made the determinations which follow.

Looking first to the examiner's rejection of claims 21 through 24 and 27 through 30 under 35 U.S.C. § 102(b) as being anticipated by Brony, we agree with the examiner with regard to claims 21, 22, 24 and 27 through 29, but not with respect to claims 23 and 30.

Reading claim 21 on the structure and method described in Brony relating to the embodiments seen in Figures 7 and 8 of that patent, we find that Brony discloses a method of accessing a port (i.e., the port or opening located at the lower end of passageway 74), the method comprising the steps of (at least between the time of an initial removal of material from the vial (V) where the plug or valve member (72) is depressed and a second removal of material therefrom where the plug or valve member is returned to its closed position and again moved to the open or depressed position by a needleless syringe (20)) moving a plug or valve member (72) to the entry position of a bore, as seen in Figures 7 and 8, wherein said bore extends to an exit position at the port; and engaging the plug or valve member (72) at said entry position, as clearly seen in Figures 7 and 8 of Brony where the plug/valve member is engaged by the tip (22) of the syringe (20), and then slidably moving the plug or valve member (72) through the bore.

Appellant's argument (brief, page 13) that there is no slidable movement of a plug through a bore in Brony, is not persuasive. Clearly in moving from the closed position seen in Figures 7 and 8 of Brony to an open position wherein medicine

stored in the vial (V) is permitted to flow from the vial to the nozzle tip (22) of syringe (20) via holes (82) and the passageway in body (71) of the plug or valve member, the plug/valve member (72) will slidably move relative to and through a portion of the bore in the stopper or link body (18 or 58) so that the holes (82) are displaced with the lower end portion of valve member (72) from the position seen in Figures 7 and 8 to a position within the vial. Appellant has provided no explanation whatsoever as to why this sliding movement of the plug or valve member in Brony relative to and through the bore in the stopper or link body (18 or 58) does not correspond to the slidable movement of the plug broadly set forth in claim 21 on appeal.

As for dependent claim 22, this claim sets forth the step of "extending said movable plug integrally across said bore to a stopper surrounding said plug." We understand this claim language to require nothing more than that the plug be movable to a position wherein the bore in the stopper is entirely closed off by the plug integrally extending across the bore and contacting a portion of the stopper surrounding the plug. As clearly seen in Figures 7 and 8 of Brony this is exactly what the plug or valve member (72) does in Brony when in the closed position.

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Appellant's mere assertion, without any explanation, that "[t]his is not in Brony" (brief, page 13), is not persuasive.

Dependent claim 24 adds to claim 21 the step of "slidably connecting said plug to said bore." The same reasoning we have set forth above in sustaining the examiner's rejection of claim 21 applies equally well here. Clearly the plug or valve member (72) in both Figures 7 and 8 of Brony is slidably connected to the bore and movable relative thereto so as to permit opening of the valve and dispensing of the medicine in the vial, followed by slidable movement of the valve member to a closed position by operation of spring (76) in Figure 7 or resilient bellows joint (80) in Figure 8.

Claims 27 and 28 respectively set forth the steps of providing the plug in the stopper with "a collar at said entry position" and providing the collar with "external Luer threads." The examiner has pointed to the upstanding annular portion seen in Figures 7 and 8 of Brony extending above the main stopper or link body (18 or 58) as corresponding to the collar of claim 27 and pointed out that Brony indicates that the upstanding annular portion is provided with a radially expanded portion defining a

Luer lock anchor (e.g., 12 in Fig. 3, but un-numbered in Figs. 7 and 8) used to secure and seal a Luer lock type syringe tip (32, as seen in Figs. 3 and 6) to the stopper. Appellant's cursory arguments and lack of clear explanation in the paragraphs bridging pages 9 and 10 of the brief provide no basis for us to conclude that the examiner's position is in any way in error. Brony does have a plug or valve member (72) which provides a blockage at an entry portion of the stopper bore and, as noted by the examiner, a collar with a Luer lock anchor or threads (12) for securing a Luer lock type syringe tip (32) to the stopper.

With regard to dependent claim 29, which sets forth the step of spanning the exit position of the bore with "a stretchable membrane," the examiner has specifically pointed to the embodiment seen in Figure 8 of Brony and apparently is of the view that the resilient bellows member (80) seen in Figure 8 constitutes a "stretchable membrane" spanning the exit position of the bore in the stopper or link body (18 or 58). We agree. Appellant's argument on page 10 of the brief that this arrangement in Brony is "entirely different than the invention in which the recited expansible member acts as a <u>retainer</u> for a plug [e.g., as in Figs. 9A-9C of appellant's application]," while

true, is of no moment, since the arrangement as shown in Figures 9A-9C of appellant's application is <u>not</u> what the broad recitation in claim 29 requires. Claim 29 merely recites a stretchable membrane spanning the exit position of the bore in the stopper, this is exactly what the stretchable bellows (80) does in the stopper or link body (18 or 58) seen in Figure 8 of Brony, wherein the bellows (80) spans the upper end of passageway (74) at the exit position of the bore in the stopper.

Based on the foregoing, we will sustain the examiner's rejection of claims 21, 22, 24 and 27 through 29 under 35 U.S.C. § 102(b) as being anticipated by Brony.

Claim 23 modifies the method as set forth in claim 21 by additionally requiring the step of "frangibly connecting said plug to said bore." As can be seen in Figures 6C, 6F and 7A of the present application, such frangible connection is in the form of a circumferential connection (311) between the plug (300) and the stopper (200), which connection must be broken or severed before the plug can be depressed into the bore (220) of the stopper (e.g., as in Fig. 7B). The examiner's position regarding this limitation (supplemental answer, page 7) is completely

without merit and totally misconstrues the requirement for a frangible connection between the plug and stopper. There is clearly no frangible connection between the plug or valve member (72) and the stopper or link body (18 or 58) in Brony. Mere contact between the valve member (72) and stopper or link body (18 or 58) in Brony does not provide a "connection" and the mere movement of the valve member relative to the stopper or link body in Brony from the contacting position seen in Figure 7 or Figure 8 to thereby open the bore to the flow of medicine from the vial (V) to the syringe (20 or 30) does not constitute a "frangible connection," as required in claim 23 on appeal. Accordingly, the examiner's rejection of claim 23 under 35 U.S.C. § 102(b) as being anticipated by Brony will not be sustained.

Independent claim 30 has also been rejected by the examiner under 35 U.S.C. § 102(b) as being anticipated by Brony. The examiner's position with regard to claim 30 is best understood by reference to page 6 of the supplemental answer, last paragraph. However, even in this paragraph the examiner has not clearly articulated how appellant's claim 30 is readable on the

embodiments seen in Figures 7 and 8 of Brony, but has merely broadly paraphrased the claim language and asserted that Brony discloses such a method. We do not agree.

The method of claim 30 can perhaps be best understood by looking to Figures 4A and 4B of the application. In these figures we see that the stopper (20) has been positioned in a neck portion of a container, with the stopper including a central throughbore (22) extending from an outer surface of the stopper to the interior of the container. There is also provided a plug (30) which extends into the bore (22) "from a position sealing said outer surface of said stopper." As can be clearly discerned from looking at Figures 4A and 4B, when access to the medicine in the container is desired, the plug (30) is depressed from its position sealing the outer surface of said stopper (Fig. 4A) into and along the throughbore (22) to permit fluid to flow between the interior of the container and the syringe (40) positioned at the outer surface of the stopper (Fig. 4B).

The examiner's bare assertion that the method of claim 30 is disclosed in Brony Figures 7 and 8 is made without explanation or factual support. While the stopper or link body (18 or 58) in

Brony includes a throughbore extending from an outer surface of the stopper/link body to the interior of the container or vial, the plug or valve member (72) of Brony does not extend into the bore from a position sealing said outer surface of said stopper as required in claim 30 on appeal. The plug or valve member (72) of Brony is contained entirely within the stopper/link body and, as we said above, does not extend "into said bore from a position sealing said outer surface of said stopper" (emphasis added), as required in appellant's claim 30. It appears the examiner has misconstrued the bottom surface of the stopper or link body (18 or 58) in Brony as being the recited "said outer surface of said stopper," which it is not. Accordingly, the examiner's rejection of claim 30 under 35 U.S.C. § 102(b) as being anticipated by Brony will likewise not be sustained.

Given the breadth of the subject matter defined in claims 21 through 30 before us on appeal, the examiner may wish to consider a search in Class 222, "Dispensing." In that regard, we note that the claims on appeal do not require a medicine in the container, or a syringe as the means for moving the plug into and along the throughbore of the stopper, or that the plug must be entirely contained within the throughbore and slidably moved along and through the bore to allow dispensing of a material from the container. Thus, the claims may be readable on dispensing a fluid from a container by dabbing or spraying, wherein a movable plug member is used to open a port and allow dispensing of a material and then subsequently acts to close and reseal the container when not in use.

As for the examiner's rejection of dependent claim 25 under 35 U.S.C. § 103(a) based on Brony, we observe that while claim 25 requires the step of providing the plug with "a non-planar external surface," contrary to appellant's apparent belief, this recitation broadly encompasses any and all of the external surfaces of the plug (i.e., top, sides and bottom) and not just that portion of the top of the plug exposed on the exterior of the stopper which is to be engaged by the end tip (41) of the syringe. In that regard, we can see from Figures 3A-3F of the application that appellant's plug (30) is generally cylindrical and thus has a "non-planar external surface," in addition to the non-planar external surface at the top of the plug where protrusions (32-1 to 32-4) are located. Like appellant's plug, the plug or valve member (72) of Brony is apparently cylindrical and will thus also have a "non-planar external surface."

Since we consider that Brony actually anticipates the subject matter of claim 25 on appeal, we are justified in sustaining the examiner's rejection of claim 25 under 35 U.S.C. § 103. As has been made clear by our reviewing Courts on numerous occasions, anticipation or lack of novelty is the ultimate or epitome of obviousness. See, in this regard, In re

<u>Fracalossi</u>, 681 F.2d 792, 794, 215 USPQ 569, 571 (CCPA 1982); <u>In</u> <u>re Pearson</u>, 494 F.2d 1399, 1402, 181 USPQ 641, 644 (CCPA 1974).

To summarize, we note that the rejection of claims 21 through 24 and 27 through 30 under 35 U.S.C. § 102(b) as being anticipated by Brony has been sustained as to claims 21, 22, 24 and 27 through 29, but not with regard to claims 23 and 30. The examiner's rejection of claim 25 under 35 U.S.C. § 103(a) has also been sustained. Thus, the decision of the examiner is affirmed-in-part.

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No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR \$ 1.136(a).

AFFIRMED-IN-PART

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APPENDIX

21. The method of accessing a port, comprising the steps of:

moving a plug to the entry position of a bore extending to an exit position of a port; and

engaging said plug at said entry position and slidably moving said plug through said bore.

- 30. A method of transferring fluid from a container, comprising the steps of:
- (a) positioning a stopper in a neck portion of a container having a central throughbore extending from an outer surface of said stopper to the interior of said container;
- (b) extending a plug into said bore from a position sealing said outer surface of said stopper; and
- (c) depressing said plug to permit fluid to flow between said interior and said outer surface.